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## **REMARKS**

Claims 1-30 are pending in the Office Action. Claims 1, 6, 12, 19, 27, and 30 have been amended. Claims 5 and 18 have been cancelled. No new matter has been added. The rejections of the claims are respectfully traversed in light of the amendments and following remarks, and reconsideration is requested.

### **Rejection Under 35 U.S.C. § 112 and § 101**

Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner writes in part that the claim "recites non-statutory subject matter making the scope of the invention unclear."

Claim 27 is also rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The Examiner writes in part that the Applicant is "positively reciting the surgeon and the patient in relation to the location of the monitor in lines 9-11."

Applicant has amended Claim 27 to no longer positively recite the surgeon and the patient in relation to the location of the monitor. Accordingly, Applicant respectfully requests that the rejections under 35 U.S.C. § 112 and § 101 be withdrawn.

### **Rejection Under 35 U.S.C. § 102(e)**

Claims 1, 2, 7, and 9 are rejected under 35 U.S.C. § 102(e) as being anticipated by Savage et al. (U.S. Patent No. 5,979,453 hereinafter "Savage"). In rejecting the claims, the Examiner writes in part:

Re: independent claim 1 and dependent claims 7, 9, 20, 22, Savage . . . discloses especially in figure 3 a method and system (40) for treating a pelvic tumor (can be in the uterus; column 2 line 33) comprising insertion into a pelvic region (shaded), positioning the ablation device (30) proximate the pelvic tumor (T), confirming the placement of the ablation device with a laparoscope (column 5 lines 33-36) and an ultrasound imaging device including a monitor (46; column 5 lines 43-49), and delivery of RF energy by electrode coupled to a RF energy source (42) through the ablation device (column 5 lines 38-43) to ablate the tumor.

Savage discloses a "needle system 40" including a "Doppler ultrasound image system 46" to provide "an image of bloodflow." (Savage, col.5, ll.38-44, emphasis added). Savage further discloses:

[T]he Doppler image greatly facilitates insertion of needle 16 distally from the sheath toward a bloodflow B of a tumor T. Once the Doppler image system indicates that the needle is adjacent the vessel which is supplying blood to the tumor, electrosurgical power is applied by ESU 42 through the needle to coagulate the bloodflow. (Savage, col.5, ll.47-52).

Savage also discloses that "the apparatus and methods of [Savage] are particularly well suited for . . . inducing shrinkage of fibroid tumors." (Savage, col.3, ll.51-54). Savage goes on to disclose that "the sheath transducer permits the surgeon to target the blood supply of a . . . tumor by placing the end of the sheath against adjacent tissues" (Savage, col.4, ll.32-35) and that "the surgeon would receive immediate feedback as to the elimination of the targeted blood flow." (Savage, col.4, ll.58-59). Thus, Savage discloses that energy is applied to a targeted bloodflow to eliminate the blood supply of a tumor. Savage does not otherwise disclose or suggest checking the placement of an electrode completely within the pelvic tumor or ablating the tumor.

Furthermore, as correctly stated by the Examiner, Savage "neglects to disclose insertion of the ablation device directly into the tumor." (Office Action, page 4).

In contrast, amended Claim 1 recites "positioning the at least one electrode of the ablation device within a pelvic tumor; confirming placement of the at least one electrode of the ablation device completely within the pelvic tumor with a laparoscope and an imaging device; and delivering energy through the at least one electrode of the ablation device to the pelvic tumor to ablate the tumor."

Therefore, because Savage does not suggest or teach all the limitations of Claim 1, Claim 1 is patentable over Savage. *what about BELT?*

Claims 2, 7, and 9 are dependent on Claim 1 and contain additional limitations that further distinguish them from Savage. Therefore, Claims 2, 7, and 9 are allowable for at least the same reasons provided above for Claim 1.

The Examiner has also rejected Claims 20 and 22 under 35 U.S.C. § 102(e) as being anticipated by Savage. Amended Claim 12 contains similar limitations as Claim 1; in particular, reciting "positioning the at least one electrode of the ablation device within a pelvic

tumor; confirming placement of the at least one electrode of the ablation device completely within the pelvic tumor with the laparoscope and the imaging device; and delivering energy to the pelvic tumor to ablate the tumor.” Accordingly, similar to Claim 1, because Savage does not suggest or teach all the limitations of Claim 12, Claim 12 is patentable over Savage. Claims 20 and 22 are dependent on Claim 12 and contain additional limitations that further distinguish them from Savage. Therefore, Claims 20 and 22 are allowable for at least the same reasons provided above for Claim 12.

For at least these reasons, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 102(e) and allowance of Claims 1, 2, 7, 9, 20, and 22.

### **Rejection Under 35 U.S.C. § 103(a)**

#### **Patentable Over Savage In View Of Burbank**

Claims 3-4 and 14-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage in view of Burbank et al. (U.S. Patent No. 6,254,601 hereinafter “Burbank”).

Burbank discloses “occluding uterine arteries.” (Burbank, Abstract). Thus, Burbank does not remedy the deficiencies of Savage noted above with regard to Claims 1 and 12.

Claims 3-4 and 14-15 are dependent on Claims 1 and 12, respectively, and contain additional limitations that further distinguish them from Savage in view of Burbank. Therefore, Claims 3-4 and 14-15 are allowable for at least the same reasons provided above for Claims 1 and 12, respectively.

#### **Patentable Over Savage In View Of Behl**

Claims 5-6, 8, and 18-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage in view of Behl (U.S. Patent No. 6,212,433).

Behl does not remedy the deficiencies of Savage noted above with regard to Claims 1 and 12. Behl discloses that the “treatment region may be identified using conventional imaging techniques capable of elucidating a target tissue . . . . Preferred is the use of high resolution ultrasound which can be employed to monitor the size and location of the tumor.” (Behl, col.6, ll.55-64). Behl further discloses that “cannula 28 is introduced through the tissue surface F until the distal tip 30 advances to point generally at the posterior of the tumor region T. The electrodes 32 are then deployed by advancing them out of the distal tip 30.” (Behl, col.10, l.66-col.11, l.3; FIG. 6C). As shown in FIG. 6C, electrodes 32 are not completely within the tumor.

Amended

In contrast, amended Claim 6 recites “deploying the plurality of arms completely within the pelvic tumor.”

Similarly, amended Claim 19 recites “deploying the plurality of arms of the ablation device completely within the pelvic tumor.”

Claims 5 and 18 have been canceled. Claims 6 and 8 are dependent on Claim 1 and contain additional limitations that further distinguish them from Savage in view of Behl. Claim 19 is dependent on Claim 12 and contains additional limitations that further distinguish them from Savage in view of Behl. Therefore, Claims 6, 8, and 19 are allowable for at least the same reasons provided above for respective Claims 1 and 12.

#### Patentable Over Savage

Claims 10-13, 16, 20-23, and 25-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage.

Savage neither suggests or makes obvious “positioning the at least one electrode of the ablation device within a pelvic tumor; confirming placement of the at least one electrode of the ablation device completely within the pelvic tumor with a laparoscope and an imaging device; and delivering energy through the at least one electrode of the ablation device to the pelvic tumor to ablate the tumor,” as recited in Claim 1.

Similarly, Savage neither suggests or makes obvious “positioning the at least one electrode of the ablation device within a pelvic tumor; confirming placement of the at least one electrode of the ablation device completely within the pelvic tumor with the laparoscope and the imaging device; and delivering energy to the pelvic tumor to ablate the tumor,” as recited in Claim 12.

Claims 10-11 are dependent on Claim 1 and contain additional limitations that further distinguish them from Savage. Claims 13, 16, 20-23, and 25-26 are dependent on Claim 12 and contain additional limitations that further distinguish them from Savage. Therefore, Claims 10-11, 13, 16, 20-23, and 25-26 are allowable for at least the same reasons provided above for respective Claims 1 and 12.

As noted above, Savage does not disclose or suggest “a laparoscope for insertion of the at least one electrode within a pelvic tumor of the patient; and an imaging device for observing a location of the at least one electrode of the ablation device completely within the pelvic tumor of the patient,” as recited in amended Claim 27.

Also, as noted above, Savage does not disclose or suggest “positioning the at least one electrode of the ablation device within at least one pelvic tumor, the at least one pelvic tumor having a diameter of at least 1 cm; confirming placement of the at least one electrode of the ablation device completely within the at least one pelvic tumor with a laparoscope and an imaging device,” as recited in amended Claim 30.

Therefore, because Savage does not suggest or teach all the limitations of Claim 27 and 30, Claims 27 and 30 are patentable over Savage.

Claims 28-29 are dependent on Claim 27 and contain additional limitations that further distinguish them from Savage. Therefore Claims 28-29 are allowable for at least the same reasons provided above for Claim 27.

#### Patentable Over Savage In View Of Schmaltz

Claim 17 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage in view of Burbank and further in view of Schmaltz et al. (U.S. Patent No. 6,190,383 hereinafter “Schmaltz”).

Schmaltz does not remedy the deficiencies of Savage in view of Burbank noted above with regard to Claim 12. Claim 17 is dependent on Claim 12 and contains additional limitations that further distinguish it from Savage in view of Burbank and further in view of Schmaltz. Therefore, Claim 17 is allowable for at least the same reasons provided above for Claim 12.

#### Patentable Over Savage In View Of Moorman

Claim 24 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage in view of Moorman et al. (U.S. Patent No. 6,355,033 hereinafter Moorman).

Moorman does not remedy the deficiencies of Savage noted above with regard to Claim 12. Claim 24 is dependent on Claim 12 and contains additional limitations that further distinguish it from Savage in view of Moorman. Therefore, Claim 24 is allowable for at least the same reasons provided above for Claim 12.

For at least these reasons, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 103(a).

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## CONCLUSION

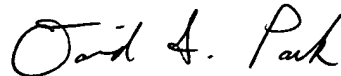
For the above reasons, Applicant believes pending Claims 1-4, 6-17, and 19-30 are now in condition for allowance and allowance of the application is hereby solicited. If the Examiner has any questions or concerns, the Examiner is hereby requested to telephone Applicant's Attorney at (949) 752-7040.

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on December 13, 2002.

  
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December 13, 2002

Respectfully submitted,



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## ATTACHMENT A

1. (Amended) A method of treating a pelvic tumor comprising:  
inserting an ablation device into a pelvic region, wherein the ablation device includes at least one electrode;  
positioning the at least one electrode of the ablation device [proximate] within [the] a pelvic tumor;  
confirming placement of the at least one electrode of the ablation device completely within the pelvic tumor with a laparoscope and an imaging device; and  
delivering energy through the at least one electrode of the ablation device to the pelvic tumor to ablate the tumor.

5. Canceled.

6. (Amended) The method of claim [5] 1, wherein the ablation device includes a plurality of deployable arms and further comprising deploying the plurality of arms completely within the pelvic tumor.

12. (Amended) A method of treating pelvic tumors comprising:  
providing a patient on an operating table;  
providing at least one monitor for a laparoscope and an imaging device, the at least one monitor being located across the operating table from a surgeon and proximate the patient's waist;  
providing an energy source and the imaging device adjacent to the at least one monitor, the energy source and the imaging device being located proximate the patient's knees;  
inserting an ablation device into a pelvic region of the patient, wherein the ablation device includes at least one electrode;  
positioning the at least one electrode of the ablation device [proximate] within a pelvic tumor;  
confirming placement of the at least one electrode of the ablation device completely within the pelvic tumor with the laparoscope and the imaging device; and  
delivering energy to the pelvic tumor to ablate the tumor.

18. Canceled.



19. (Amended) The method of claim [18] 1, wherein the ablation device includes a plurality of deployable arms and further comprising deploying the plurality of arms of the ablation device completely within the pelvic tumor.

27. (Amended) A surgical system for ablating pelvic tumors in a patient, the system comprising:

an ablation device for insertion into a pelvic region of a patient, wherein the ablation device includes at least one electrode;

an energy source coupled to the ablation device for providing energy to the ablation device;

a laparoscope for insertion [into] of the at least one electrode within a pelvic tumor of the patient; and

an imaging device for observing a location of the at least one electrode of the ablation device completely within the pelvic tumor of the patient,

wherein the laparoscope and the imaging device are connected to at least one monitor, the at least one monitor being located [across the] along a first side of an operating table [from a surgeon and proximate the patient's waist], and wherein the energy source and the imaging device are located adjacent the [first and second monitors and proximate the patient's knees] at least one monitor along the first side of the operating table.

30. (Amended) A method of treating pelvic tumors comprising:

inserting an ablation device including at least one electrode into a puncture site in a pelvic region, the puncture site being approximately 1 mm to 2 mm in diameter;

positioning the at least one electrode of the ablation device [proximate] within at least one pelvic tumor, the at least one pelvic tumor having a diameter of at least 1 cm;

confirming placement of the at least one electrode of the ablation device completely within the at least one pelvic tumor with a laparoscope and an imaging device;

delivering RF energy to the ablation device; and

heating the at least one pelvic tumor to a temperature between approximately 85 °C and approximately 100 °C for between approximately 7 and 14 minutes,

wherein from the puncture site substantially all of the at least one pelvic tumor is ablated.

## **ATTACHMENT B**

Paragraph 0008 on page 3, between "located" and "the" insert --across--.

[0008] In accordance with still another embodiment of the present invention, a surgical system for treating pelvic tumors in a patient lying on an operating table includes an ablation device, an energy source, a laparoscope, and an imaging device. The energy source is coupled to the ablation device and provides energy to the device to ablate a pelvic tumor. The laparoscope and the imaging device are connected to at least one monitor. The at least one monitor is located across the operating table from a surgeon and proximate the patient's waist, while the energy source and imaging device are located alongside the at least one monitor and proximate the patient's knees.

Paragraph 0034 on page 9, between "and" and "into" cancel "the".

[0034] At step 76, after the surgeon has stabilized the uterus and located the tumors, the surgeon guides ablation device 22 into the uterus and [the] into a wall of the uterus. The surgeon may guide ablation device 22 by changing the position of the uterus relative to ablation device 22. In addition, the surgeon may rotate the ablation device for better penetration of the uterine wall with less movement of the uterus. Ablation device 22 has a plurality of markings (not shown) that enable the surgeon to note the depth of penetration of device 22. Confirmation of the location and placement of ablation device 22 are provided by both laparoscope 12 and ultrasound probe 24.